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February 11, 2020

VIA EMAIL

TIME SENSITIVE REQUEST

Rigoberto Roca, MD
Acting Director
Division of Anesthesiology, Addiction Medicine, and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

RE: CBE-30 Supplement for Manufacturing Site Change for NDA 209575
for Numbrino® (cocaine hydrochloride) nasal solution, 4% (40 mg/mL)

Dear Dr. Roca:

I am writing to you regarding an urgent, time-sensitive matter. It has come to our attention that Cody Laboratories ("Cody") and/or its parent Lannett Company ("Lannett") may have filed a 30 day changes-being-effected ("CBE-30") supplement to NDA 209575 for a manufacturing site change for its recently approved drug product Numbrino® (cocaine hydrochloride) nasal solution, 4% (40 mg/mL). Specifically, we understand that Cody/Lannett is proposing to move the manufacturing of Numbrino® from its long since closed manufacturing facility in Cody, Wyoming to a facility in Carmel, New York. As discussed below, FDA should immediately classify the manufacturing site change as a major change and require FDA approval of the supplement before distribution of the drug product manufactured at the Carmel facility.¹

This matter needs your urgent attention because if the CBE-30 supplement is not immediately converted to a prior approval supplement ("PAS"), Cody/Lannett may soon start distributing a cocaine hydrochloride product (applied intranasally) into interstate commerce from a facility never inspected for such a drug. In light of the significant legal issues raised by the CBE-30 Supplement, I have cc'd the Deputy Chief Counsel for Biologics and Drugs, Amanda Edmonds, on this letter. Likewise, given the potential gaming of the pre-approval inspection process, I have cc'd the Director of the Office of Pharmaceutical Quality, Michael Kopcha, on this letter.

¹ See 21 CFR 314.70 (requiring major changes to be submitted in a PAS).

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Cody Laboratories previously manufactured unapproved cocaine hydrochloride nasal solutions at its facility at 601 Yellowstone Avenue, Cody, Wyoming from approximately 2008 until June 2019. Cody Laboratories submitted an NDA under 505(b)(2) for the drug product in September 2017, listing the facility in Cody, Wyoming in the Chemistry, Manufacturing, and Controls (“CMC”) section as the location where Numbrino® would be manufactured. For purposes of the specific action requested by this letter – i.e., Cody Laboratories’ CBE-30 being immediately converted to a PAS – the following dates and events are of significance:

- December 2017: A redacted EIR from an inspection of Cody’s manufacturing facility in Cody, Wyoming in December 2017 indicates that FDA conducted a pre-approval inspection for the Numbrino® NDA.²
- July 2018: Cody Laboratories received a Complete Response Letter (“CRL”) dated July 20, 2018, indicating an agency determination that it would not approve the application in its present form.
- June 2019: The following three significant events occurred in June:
 - Cody Laboratories ceased manufacturing its unapproved cocaine hydrochloride drug product. According to Lannett filings with the SEC, at the “request of the FDA to cease manufacturing and distributing our unapproved cocaine hydrochloride solution product as a result of an approved product on the market, the Company committed to not manufacture or distribute cocaine hydrochloride 10% solution, which has not been sold during Fiscal 2019, as of April 15, 2019. The Company also ceased manufacturing its unapproved cocaine hydrochloride 4% solution on June 15, 2019.”³
 - On June 12, 2019, well before its NDA for Numbrino® was approved by FDA, Cody/Lannett announced that it had decided to cease operations and close Cody Laboratories’ manufacturing facility at 601 West Yellowstone.⁴
 - Cody/Lannett responded to the June 2018 CRL on June 21, 2019.
- September 2019: Less than three months after responding to the June 2018 CRL, Lannett announced it had closed all drug manufacturing operations at Cody Laboratories in Cody, Wyoming.⁵

2 FDA Establishment Inspection Report for Cody Laboratories, Inc., 601 Yellowstone Ave., Cody, WY, FEI 3003149772, December 4-8, 2017, FDA investigators Nayan J. Patel and Christopher M. Jenner.

3 Lannett Company, Inc., U.S. SEC Form 10-Q, November 7, 2019, accessed at <http://app.quotemedia.com/data/downloadFiling?webmasterId=101533&ref=114611276&type=PDF&symbol=LCI&companyName=Lannett+Co+Inc&formType=10-Q&dateFiled=2019-11-07&CK=57725>.

4 See *Cody Labs to Shut Down*, Cody Enterprise (June 12, 2019), accessed at http://www.codyenterprise.com/news/local/article_fl8304e-8d50-11e9-a6c3-131a616609b5.html.

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- November 2019: Lannett discussed the manufacturing of its cocaine product at the Silarx facility in Carmel, New York in a recent earnings call.⁶
- January 2020: Notwithstanding the fact that the manufacturing facility identified in Cody Laboratories' NDA was closed and that manufacturing operations had been moved to a new site in Carmel, New York, FDA approved Numbrino® by a letter (dated January 10, 2020) addressed to Cody Laboratories at 9000 State Road, Philadelphia, PA.

Per the timeline described above, it is very clear that Cody Laboratories' NDA required a pre-approval inspection and that Cody/Lannett closed the manufacturing site identified in the NDA (and inspected by FDA) and transferred the product to another facility in Carmel, New York months before the NDA was approved. It is equally clear that Cody/Lannett should have notified FDA of the site change while the application was pending and should have listed this new site in its NDA filing. Under the Food, Drug and Cosmetic Act (FD&C Act), FDA may approve an NDA only if the methods used in, and the facilities and controls used for, the manufacture, processing, packing, and testing of the drug are found adequate to ensure and preserve its identity, strength, quality, and purity."⁷ At the time of the approval, the "methods used in, and the facilities and controls used for . . . the manufacture" of Numbrino® could not have been found adequate to ensure and preserve its identity because the manufacturing site listed in the CMC was closed.

Since FDA approved Cody Laboratories' NDA, it seems almost certain that the Agency was unaware that Cody/Lannett had closed the Cody, Wyoming facility. Indeed, had it known it would have required Cody/Lannett to amend its NDA to include the new manufacturing site (and related data associated with the new site) and, because a pre-approval inspection was required for the NDA, would likely have required an inspection of the new manufacturing site. Had Cody/Lannett appropriately listed the new manufacturing site in its NDA filing in late 2019, this would have been a major amendment to the NDA. In any event, it would be entirely inappropriate to allow Cody/Lannett to manufacture the drug for the very first time in a different facility on the other side of the country without an inspection. Indeed, such allowance would be inappropriate particularly if Cody/Lannett was intentionally gaming the NDA-approval process by telling FDA (through information contained in its NDA) that it was going to manufacture the product in the facility inspected by FDA (i.e., the facility in Cody, Wyoming) while it was simultaneously generating data in another facility (i.e., the facility in Carmel, New York) for purposes of submitting a site manufacturing supplement to FDA immediately after the NDA was approved.

⁵ See *Cody Labs Finalizes Closure*, Gillette News Record (September 3, 2019), accessed at https://www.gillette news record.com/news/wyoming/article_d583811b-0084-5d8e-a393-a7834d079ab2.html.

⁶ See <https://seekingalpha.com/article/4303477-lannett-companys-lci-ceo-tim-crew-g1-2020-results-earnings-call-transcript?part=single>.

⁷ FD&C Act § 505(d) (21 U.S.C. §§ 355(d)(3)).

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As noted above, Cody/Lannett is now seeking to manufacture its approved Numbrino for the first time at its facility in Carmel, New York. Again, such a change should require FDA prior approval and an FDA inspection.⁸ In order to manufacture Numbrino in the Carmel, New York facility, Lannett would have had to either disassemble, ship across the country, reassemble, and re-qualify the manufacturing and packaging equipment it used in Cody, Wyoming or set up and qualify existing equipment used to manufacture and package other liquid solutions at Carmel, New York. To the best of our knowledge, Lannett manufactures no other nasal solutions in the Carmel facility (or, for that matter, any otic, ophthalmic, or topical solutions) and manufactures only one oral solution that is packaged in a glass bottle.

Cocaine hydrochloride is a solution for intranasal application. The 4% nasal solution is supplied in a single-use 4 mL (160 mg/4 mL) glass bottle as well as a multiple-use 10 mL (400 mg/10 mL) plastic bottle. Filling and capping glass bottles is a more specialized operation that presents different issues and practices than are employed to fill and cap plastic bottles for oral solutions. For example, a high variation in tare weight is more common with glass bottles and can create difficulties using in-line checkweighers that are typically used plastic bottles. Bottles of cocaine hydrochloride topical solution for intranasal application require 100% weighchecking for rejecting underfilled and overfilled bottles.

Another unique condition presented by the manufacture of Cocaine hydrochloride topical solution relates to its status as a Schedule II controlled substance and the need for a leak proof seal on the bottles. The December 2017 EIR notes that Cody received over 100 complaints related to leaking bottles in 2014, which led the company to switch to a new in-line capper process in 2015. Nevertheless, the FDA investigator noted that the company had received three new complaints with lots manufactured after the changed process was initiated. FDA must inspect the Carmel, New York facility to confirm that the site has properly validated the equipment and design of the container closure caps for glass bottles. These issues have a substantial potential to have an adverse effect on the quality, safety, and effectiveness of the drug product and thus a supplement submission and approval prior to distribution of the product made using the change is required under 21 C.F.R. 312.70(b).

The fact that Cody/Lannett also was required to completely revalidate its manufacturing and packaging processes on equipment relocated from across the country or on new equipment, revalidate its test methods in the Carmel, New York quality control laboratory, and presumably train new employees to manufacture, test, and package the company's first NDA product are also compelling reasons for FDA not accepting the site change as a CBE-30. Everything the Agency verified during the December 2017 inspection – the process validation programs and data, the verification of processing lines, analytical methods, and stability batches – has presumably now been redone at the Carmel facility with new personnel and possibly different manufacturing equipment. Finally, Cody/Lannett should not be rewarded after gaming the new drug approval process – which it did by closing the manufacturing facility that was listed in its NDA (and subject to the pre-approval inspection) and then failing to amend its NDA with a new

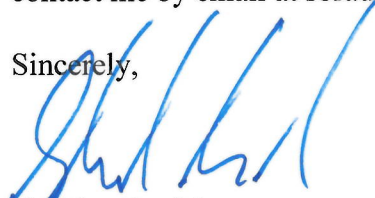
⁸ It has been almost two years since the last FDA inspection of the Carmel facility (which occurred on February 28, 2018). See FDA Inspection Classification Database, accessed at <https://www.accessdata.fda.gov/scripts/inspsearch/>.

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manufacturing site prior to approval – by being allowed to make a manufacturing site change immediately after approval through a CBE-30.

We appreciate your prompt attention to this important matter. If you have any questions, please contact me by email at sbradshaw@kslaw.com or by phone at 202-626-9225.

Sincerely,



Sheldon Bradshaw
Partner
King & Spalding

cc: Amanda Edmonds
Deputy Chief Counsel for Biologics and Drugs
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